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8 **BEFORE THE ARIZONA STATE BOARD OF PHARMACY**

9
10 In the matter of

11 **PHOENIX CHILDREN'S HOSPITAL**
12 **OUTPATIENT PHARMACY**

13 Holder of Pharmacy Permit No. Y001644
14 In the State of Arizona.

Board Case No. 15-0004-PHR

**CONSENT AGREEMENT FOR
PROBATION, CIVIL PENALTY AND
INSPECTIONS**

15 In the interest of a prompt and judicious settlement of this case, consistent with the
16 public interest, statutory requirements and the responsibilities of the Arizona State Board
17 of Pharmacy ("Board") under A.R.S. § 32-1901, et. seq., Phoenix Children's Hospital
18 Outpatient Pharmacy ("Respondent"), holder of Pharmacy Permit No. Y001644 in the
19 State of Arizona and the Board enter into the following Recitals, Findings of Fact,
20 Conclusions of Law and Order ("Consent Agreement") as a final disposition of this
21 matter.

22 **RECITALS**

23
24 1. Respondent has read and understands this Consent Agreement and has had
25 the opportunity to discuss this Consent Agreement with an attorney, or has waived the
26 opportunity to discuss this Consent Agreement with an attorney.

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2 2. Respondent understands that it has a right to a public administrative hearing
3 concerning this matter at which hearing it could present evidence and cross examine
4 witnesses. By entering into this Consent Agreement, Respondent knowingly and
5 voluntarily relinquishes all right to such an administrative hearing, as well as rights of
6 rehearing, review, reconsideration, appeal, judicial review or any other administrative
7 and/or judicial action, concerning the matters set forth herein.

8 3. Respondent affirmatively agrees that this Consent Agreement shall be
9 irrevocable.

10 4. Respondent understands that this Consent Agreement or any part of the
11 agreement may be considered in any future disciplinary action by the Board against it.

12 5. Respondent understands this Consent Agreement deals with Board
13 Complaint No. 4237 involving allegations of unprofessional conduct against Respondent.
14 The investigation into these allegations against Respondent shall be concluded upon the
15 Board's adoption of this Consent Agreement.

16 6. Respondent understands that this Consent Agreement does not constitute a
17 dismissal or resolution of any other matters currently pending before the Board, if any.
18 and does not constitute any waiver, express or implied, of the Board's statutory authority
19 or jurisdiction regarding any other pending or future investigation, action or proceeding.

20 7. Respondent also understands that acceptance of this Consent Agreement
21 does not preclude any other agency, subdivision, or officer of this State from instituting
22 any other civil or criminal proceedings with respect to the conduct that is the subject of
23 this Consent Agreement.

24 8. Respondent acknowledges and agrees that, upon signing this Consent
25 Agreement and returning this document to the Board's Executive Director, it may not
26

1 revoke its acceptance of the Consent Agreement or make any modifications to the
2 document regardless of whether the Consent Agreement has been signed by the Executive
3 Director. Any modification to this original document is ineffective and void unless
4 mutually agreed by the parties in writing.

5 9. This Consent Agreement is subject to the approval of the Board and is
6 effective only when accepted by the Board and signed by the Executive Director. In the
7 event that the Board does not approve this Consent Agreement, it is withdrawn and shall
8 be of no evidentiary value and shall not be relied upon nor introduced in any action by any
9 party, except that the parties agree that should the Board reject this Consent Agreement
10 and this case proceeds to hearing, Respondent shall assert no claim that the Board was
11 prejudiced by its review and discussion of this document or any records relating thereto.

12 10. If a court of competent jurisdiction rules that any part of this Consent
13 Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement
14 shall remain in full force and effect.

15 11. Respondent understands that this Consent Agreement is a public record that
16 may be publicly disseminated as a formal action of the Board and may be reported as
17 required by law to the National Practitioner Data Bank and the Healthcare Integrity and
18 Protection Data Bank.

19 12. Respondent understands that any violation of this Consent Agreement
20 constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-
21 1901.01(B) (20) and A.R.S. §- 1927(A) (1).

22 13. Respondent agrees that the Board will adopt the following Findings of Fact,
23 Conclusions of Law and Order.
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1 ACCEPTED AND AGREED BY RESPONDENT

2 Robert Huley
3 Phoenix Children's Hospital Outpatient Pharmacy

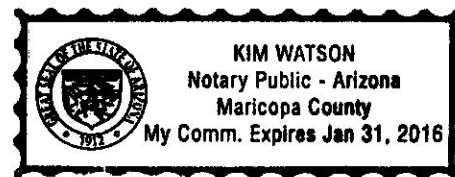
Dated: 11/7/14

4 Subscribed and sworn to before me in the County of Maricopa, State
5 of Arizona, this 7th day of November, 2014, by Phoenix
6 Children's Hospital Outpatient Pharmacy.

7 Kim Watson
8 NOTARY PUBLIC

9 My Commission Expires:

10 January 31, 2016



11 **FINDINGS OF FACT**

12
13 1. The Board is the duly constituted authority for licensing and regulating the
14 practice of pharmacy in the State of Arizona.

15 2. Respondent is the holder of permit number Y001644 to operate as a
16 pharmacy in the State of Arizona.

17 3. During all relevant times to these findings, Respondent operated as Phoenix
18 Children's Hospital Outpatient Pharmacy located at 1919 E. Thomas Rd., Phoenix,
19 Arizona.

20 4. On or about May 16, 2014 through June 2, 2014 Pharmacy Board
21 compliance officers received information regarding possible violations by Respondent
22 relating to supervision of compounding technicians and improper compounding practices.

23 5. On or about June 2, 2014 Pharmacy Board compliance officers conducted
24 an inspection of Respondent and interviewed Lyle Brauner, pharmacist-in- charge, and
25 Jacqueline Cavanagh, pharmacist, regarding the possible violations.

26 6. During the inspection on June 2, 2014 Pharmacy Board compliance officers

1 found that necessary equipment and protective apparel including ventilation hoods and
2 gowns were not provided for the compounding of hazardous substances at Respondent.
3 Respondent contracted with a qualified entity to operate and manage the pharmacy.
4 Neither Respondent nor this entity were aware of the hazardous compounding, and based
5 on the employment of a properly licensed pharmacist in charge who was responsible for
6 compliance with applicable law and the known lack of proper equipment, had no reason to
7 believe that such inappropriate activity was occurring. Once Respondent and the
8 contracted entity were made aware of the activity they ordered it to cease immediately.

9 7. During the inspection on June 2, 2014 Pharmacy Board compliance officers
10 requested that the pharmacist in charge provide records including a new employee check
11 list for technician E. S. and a copy of the program used to train technicians employed by
12 Respondent who perform compounding activities. The pharmacist in charge was unable
13 to provide Pharmacy Board compliance officers with these documents as requested.
14 Respondent and the contracted entity required the pharmacist in charge to prepare a new
15 employee checklist for each employee and had received compounding training certificates
16 for technicians. The technicians' performance reviews also included references to on-site
17 compounding training.

18 8. During the inspection on June 2, 2014 Pharmacy Board compliance officers
19 reviewed the compounding logs for nine (9) preparations containing at least one
20 hazardous products and noted numerous entries lacking documentation of the technician
21 or pharmacist who prepared and the pharmacist who verified the compounded preparation.

22 9. During the inspection on June 2, 2014 Pharmacy Board compliance officers
23 interviewed pharmacist Jacqueline Cavanagh who worked at Respondent and who
24 voluntarily informed them that, based on instruction from the pharmacist in charge, on
25 some occasions she would not verify compounds prepared by technicians, but, despite the
26 pharmacist in charge's instruction, she did insist that the technicians ensure that she verify

1 compounds with product or quantity changes.

2 10. There was never any report of patient harm from any of the compounds
3 prepared in the pharmacy.

4 11. Respondent has appropriately addressed all of the issues identified in the
5 inspection report and the Board has been assured that the current pharmacist in charge,
6 Jacqueline Cavanagh, will operate the pharmacy in a compliant manner.

7 **CONCLUSIONS OF LAW**

8 1. The Board possesses jurisdiction over the subject matter and over
9 respondent pursuant to A.R.S. § 32-1901 *et seq.*

10 2. The Board may discipline a pharmacy permittee for engaging in
11 unprofessional conduct pursuant to A.R.S. § 32-1927.02 (A) (1).

12 3. The conduct and circumstances described above constitutes unprofessional
13 conduct pursuant to A.R.S. § 32-1901.01(A) (5) (Violating a federal or state law or
14 administrative rule relating to the manufacture, sale or distribution of drugs, devices
15 poisons, hazard substances or precursor chemicals); specifically, A.A.C. R4-23-410 (C)
16 (1) and A.A.C. R4-23-410 (I) (1) (a) (i-iii).

17 **ORDER**

18
19 Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY
20 ORDERED THAT:

21 1. Respondent shall pay a civil penalty of \$5,000.00 within 180 days of the
22 effective date of this Order.

23 2. Respondent is placed on probation for a period of two years upon the
24 adoption of this Consent Agreement by the Board.

25 3. Respondent shall be subject to two random unannounced inspections by
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1 Board staff within one year of the effective date of this Consent Agreement.

2 4. Respondent shall produce complete policies and procedures upon an
3 inspection conducted pursuant to Paragraph 3.

4 5. Respondent shall pay all costs associated with complying with this Consent
5 Agreement.

6 6. Respondent shall not appear to have the probation lifted prior to 90 days
7 before the end of the two year probation.

8 DATED this 10 day of DECEMBER 2014.

9 ARIZONA STATE BOARD OF PHARMACY

10 (Seal)

11
12 By


13 HAL WAND R.Ph.
14 Executive Director

15 ORIGINAL OF THE FOREGOING FILED
16 this 10 day of December, 2014, with:

17 Arizona State Board of Pharmacy
18 1616 W. Adams Street
19 Phoenix, Arizona 85007

20 EXECUTED COPY OF THE FOREGOING MAILED
21 BY CERTIFIED MAIL
22 this 10 day of December, 2014, to:

23 Phoenix Children's Hospital Outpatient Pharmacy
24 1919 E. Thomas Road
25 Phoenix, Arizona 85028
26 Respondent

1 Roger Morris
Christine Cassetta
2 Quarles & Brady, LLP
One Renaissance Square
3 Two North Central Avenue
Phoenix, Arizona 85004
4 Attorneys for Respondent

5 EXECUTED COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL

6 this 10 day of December, 2014, to:

7 Montgomery Lee
Assistant Attorney General
8 1275 W. Washington Street, CIV/LES
Phoenix, Arizona 85007
9 Attorney for the Board

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